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DISTRICT OF DELAWARE

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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VIACELL, INC., CRYO-CELL
INTERNATIONAL, INC. and CORCELL,
INC.

Plaintiffs,

v.

PHARMASTEM THERAPEUTICS, INC.,

Defendant.

Civil Action No. 04-1335-GMS

**PHARMASTEM THERAPEUTICS, INC.'S OPPOSITION TO VIACELL,
INC.'S MOTION FOR ENTRY OF A PRELIMINARY INJUNCTION**

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Exhibit C

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I. SUMMARY OF ARGUMENT

PharmaStem Therapeutics, Inc. ("PharmaStem") respectfully requests that this Court deny ViaCell, Inc.'s ("ViaCell") motion for a preliminary injunction ("ViaCell's motion") because through litigation and the settlement thereof, PharmaStem is rightfully enforcing its presumptively valid intellectual property rights.¹ By its motion, ViaCell is attempting to use the judicial system to strip PharmaStem of the very rights explicitly granted to it by Article I of the U.S. Constitution and the U.S. Patent and Trademark Office ("Patent Office") in issuing presumptively valid U.S. Patents No. 6,461,645 ("the '645 Patent"), No. 6,569,427 ("the '427 Patent"), and No. 6,605,275 ("the '275 Patent"). This is simply the next move by ViaCell and two other industry titans, who have decided to forgo legitimate licensing, and instead use the court system to try to "run out the clock" on PharmaStem's patents. ViaCell's motion must fail because it is fatally flawed procedurally due to the existence of parallel litigations in Massachusetts, Florida and Pennsylvania, barred by ViaCell's unclean hands, and substantively meritless because PharmaStem has the right to bring good-faith suits to protect its intellectual property rights and to settle, in good faith, potential claims against potential infringers.

As a threshold matter, ViaCell's motion for a preliminary injunction can and should be denied because the underlying claims by ViaCell and its fellow co-plaintiffs, Cryo-Cell and CorCell, are barred by the Doctrine of Compulsory Counterclaim and the First Filed Rule, and as such, ViaCell was obligated to bring this request for a preliminary injunction in the District Court for the District of Massachusetts, not in the District Court for the District of Delaware.² Allowing ViaCell's motion (and the underlying action) to continue in the District of Delaware will invite inconsistent verdicts in the District Courts for the Districts of Delaware and

¹ Since filing this motion, the complaint was amended to add Cryo-Cell International, Inc. ("Cryo-Cell") and CorCell, Inc. ("CorCell").

² On or before October 29, 2004, PharmaStem will seek to dismiss the above-captioned action on these and other grounds. Given that PharmaStem's motion to dismiss may be dispositive, PharmaStem requests, as a procedural matter, that the Court hear that motion first.

Massachusetts, Florida, and Pennsylvania where parallel, first-filed litigation is pending.

Additionally, ViaCell's unclean hands prohibit its claims for equitable relief.

Substantively, ViaCell's motion for injunctive relief should also be denied, (1) because ViaCell is not likely to succeed on the merits on its Sherman Act or Massachusetts Unfair Competition claims as PharmaStem has a demonstrable, good-faith belief in the validity, enforceability, and infringement of its patents, (2) because ViaCell cannot establish that it will suffer irreparable harm if the injunction is denied, (3) because granting preliminary relief will result in greater harm to PharmaStem than the harm claimed by ViaCell in the absence of the injunction, and (4) because the public interest does not favor granting a preliminary injunction. At the heart of this dispute is one single, dispositive fact: PharmaStem's patents *are in fact* grants of a *temporary legal monopoly* explicitly awarded by the Patent Office. PharmaStem has both the *right* under black-letter U.S. patent law and the *obligation* under its license agreements to enforce its patents by bringing suit against (or licensing or settling with) any and all parties that PharmaStem, in good-faith, believes infringe its patents. Even if this Court concludes that reasonable minds could differ as to whether physicians or health care providers do, in fact, infringe PharmaStem's Patents, PharmaStem's good-faith activities in enforcing the intellectual property rights conferred upon it by the Patent Office cannot subject it to liability under the Sherman Act, or Massachusetts' Unfair and Deceptive Trade Acts and Practices statute. Notably, three of these patents, which are the subject of the Amnesty Agreement, have never been before this Court and no Court has ever ruled on provider liability of any of PharmaStem's Patents.

For all of these reasons, and for the reasons outlined below, PharmaStem respectfully requests that this Court allow it to continue to enforce its presumptively valid, enforceable intellectual property rights during the pending litigation of ViaCell's claims of antitrust and unfair competition by denying ViaCell's request for a preliminary injunction.

A. Rovner,⁴ Exh. A. In the 2004 Massachusetts action, PharmaStem alleged that ViaCell and the Massachusetts codefendants were liable for direct infringement of, contributory infringement of, and/or inducement to infringe PharmaStem's '645 and/or '427 Patents for the collection and storage of umbilical cord blood for future therapeutic use. ViaCell and the Massachusetts codefendants asked PharmaStem for a sixty-day extension of time to answer the Complaint, which PharmaStem granted. Rovner Decl., Exh. B.

On October 5, 2004, more than two months *after* PharmaStem filed the 2004 Massachusetts action and before answering PharmaStem's complaint, ViaCell filed this complaint in this Court, alleging, *inter alia*, violations of federal antitrust law and Massachusetts unfair competition law arising from PharmaStem's lawsuit against ViaCell and the Massachusetts codefendants, and from PharmaStem's attempts to license and enforce its patents, including the two patents at issue in the 2004 action. Three days after filing its complaint, ViaCell moved for a preliminary injunction in Delaware based on its newly filed action.

III. FACTUAL BACKGROUND

ViaCell's motion for a preliminary injunction depends upon its central accusation that PharmaStem is wrong regarding the potential liability of medical care providers, including obstetricians and physicians, for infringement of PharmaStem's Patents. ViaCell's motion for a preliminary injunction hinges on a finding that PharmaStem could have no good-faith belief in potential liability of providers under any theory (direct, contributory, or inducement to infringe). The key to each of the following statements and actions about which ViaCell complains is whether providers may be found liable of infringement of PharmaStem's Patents.

The allegedly offending statements are as follows:

- In a June 1, 2004 letter to obstetricians, PharmaStem informed them of PharmaStem's position regarding providers' potential liability for patent

⁴ All lettered exhibits to this Memorandum of Points and Authorities in Opposition to ViaCell's Motion for a Preliminary Injunction will be exhibits to the Declaration of Philip A. Rovner ("Rovner Decl."), filed contemporaneously herewith.

infringement if they deal with unlicensed cord blood banks, such as ViaCell, Cryo-Cell and CorCell. ViaCell's motion, Exh. 1.

- In a August 2, 2004 PharmaStem announced in a press release ("Press Release") that PharmaStem initiated a number of new lawsuits against unlicensed cord blood banks, including ViaCell, Cryo-Cell, CorCell, as well as providers. ViaCell's motion, Exh. 3.
- On August 18, 2004 PharmaStem sent a letter offering to settle PharmaStem's suit against a number of physicians who PharmaStem had sued for patent infringement. As one term of that proposed agreement, the Physicians were to agree not to undertake the activities (collecting blood for unlicensed private banks and marketing their services) for which PharmaStem had brought suit. ViaCell's motion, Exh. 4.
- On August 20, 2004, PharmaStem sent a letter and "Amnesty Agreement" to various providers, which provided that PharmaStem covenants not to sue them if they agree not to collect cord blood or market or offer the service of cord blood collection in connection with certain unlicensed cord blood banks, such as ViaCell, Cryo-Cell and CorCell. ViaCell's motion, Exh. 5-6.
- On September 14, 2004 PharmaStem sent a letter to some of those providers against whom it had brought suit offering to settle those lawsuits on the terms set forth in the Amnesty Agreements. ViaCell's motion, Exh. 7.
- On September 20, 2004 PharmaStem issued a press release which set forth PharmaStem's understanding of this Court's post-trial rulings in the 2002 Delaware action and the arguments set forth by defendants at that trial. ViaCell's motion, Exh. 8.
- On September 22, 2004, PharmaStem (through its Counsel) sent a letter to the American College of Obstetricians and Gynecologists ("ACOG"). This letter set forth the fact that PharmaStem had brought suit against a number of providers, that PharmaStem's amnesty program had been joined by hundreds of physicians, and that another professional society had recommended that its members join the amnesty program as a precautionary measure against being named in a lawsuit. ViaCell's motion, Exh. 9

See ViaCell's motion at 7-9. In sum, the behavior that ViaCell complains about is as follows: (1) PharmaStem has sued a number of providers and offered to settle those suits with them if they agree to stop the actions for which they were sued in the first place, (2) PharmaStem has widely disseminated facts regarding these suits, and (3) PharmaStem has widely disseminated an "amnesty" offer to any provider who wishes to preclude the possibility of suit by agreeing, in

advance, not to perform the actions upon which PharmaStem is basing its suits against providers.⁵

ViaCell has also set forth a self-serving affidavit of Chris Adams (ViaCell's Senior Vice President of Business Development)("Mr. Adams") as its basis for establishing the harm of PharmaStem's actions in the marketplace. *See* Affidavit of Chris Adams in Support of ViaCell's motion. ("Adams affidavit"). The Adams affidavit sets forth two distinct claims: (1) that ViaCell has been contacted by a certain number of doctors, hospitals, and other providers in the past few months to terminate business relationships, and (2) that ViaCell has been contacted by a number of doctors, hospitals, and other providers during the same span of time regarding PharmaStem's claims. The Adams affidavit does not put these two sets of disparate facts together, however.⁶ In fact, the Adams affidavit does not specifically tie a single doctor or health care provider to both (a) a statement regarding PharmaStem's litigation, and (b) a decision to cease doing business with ViaCell.

In addition, the Adams affidavit does not identify by name a single hospital, doctor, or other provider. As a result, PharmaStem has been prevented from speaking to any allegedly affected doctor, hospital, or provider, and unable to exam the veracity of the hearsay ViaCell relies upon. Indeed, ViaCell does not present any such evidence in support of its motion. All of this, of course, leaves open the fundamental question as to whether ViaCell has suffered any

⁵ To the extent ViaCell also complains about the *implications* of the facts PharmaStem has chosen to include in its press releases, PharmaStem maintains that all statements set forth in its press releases were either objectively true, or were lay opinion, and as such, they are not actionable. It is, of course, the nature of press releases to be somewhat one-sided. For example, ViaCell, in its press releases and other documents widely disseminated to the public, also set forth those facts which are most favorable to it and leaves out those facts favorable to PharmaStem. *See* Rovner Decl., Exh. C, F, G, I (ViaCell misleadingly asserts that "a Federal Court in Delaware overturned in its *entirety* an earlier judgment against ViaCell"). The jury's verdict in its entirety, as statements in these documents imply, was not overturned.

⁶ To the extent that the Adams affidavit attempts to draw a connection, it is mere conjecture, and without the opportunity to depose the "doctors" in question, as they were not identified in ViaCell's motion, it is also inadmissible hearsay.

harm to date or can prove that it will suffer any harm in the future. Further relevant facts are set forth below.

IV. ARGUMENT

A. VIACELL'S MOTION FOR PRELIMINARY INJUNCTION AND ITS UNDERLYING SUIT SHOULD BE DISMISSED BECAUSE VIACELL COMES TO THIS COURT WITH UNCLEAN HANDS.

1. The Underlying Complaint And This Pendant Motion Should Be Dismissed Because ViaCell And Its Fellow Plaintiffs In The Underlying Action Are Forum Shopping.

Forum shopping by defendants is prohibited by Rule 13(a) of the Federal Rules of Civil Procedure, which is set forth as follows: "A pleading *shall state as a counterclaim any claim* which at the time of serving the pleading the pleader has against any opposing party, *if it arises out of the transaction or occurrence that is the subject matter of the opposing party's claim[...]*" Fed. R. Civ. P. 13(a) (emphasis added). ViaCell and its fellow plaintiffs in this action are forum shopping, and in so doing, have invited this Court to make rulings that could be inconsistent with rulings in parallel litigation in three other Federal District Courts. Nothing other than forum shopping can explain why ViaCell, Cryo-Cell and CorCell elected to bring antitrust claims in the District Court for the District of Delaware regarding PharmaStem's enforcement of patents for which enforceability, validity, and infringement are *already at issue* before District Courts for the District of Massachusetts, the Eastern District of Pennsylvania, and the Middle District of Florida.

Regarding ViaCell particularly, it is procedurally lethal to ViaCell's motion for a preliminary injunction (because of the illegitimacy of the Complaint upon which the motion for a preliminary injunction was sought) that PharmaStem brought an action against ViaCell and various medical providers on two of the patents at issue in the instant suit in the District of Massachusetts on July 28, 2004, more than *two months* before ViaCell brought this suit. Rather than presenting its claims as counterclaims in the first-filed Massachusetts action, ViaCell has asked this Court to grant a preliminary injunction brought, in part, under *Massachusetts* law for

activity which allegedly took place *in* Massachusetts, in spite of the existence of an earlier-filed lawsuit in the *District of Massachusetts* asserting infringement of two of the patents at issue here. There is no reason to permit such blatant forum shopping.

2. The Doctrine Of Compulsory Counterclaims And The First Filed Rule Dictates That ViaCell's Claims Be Brought As Counterclaims In PharmaStem's Massachusetts Action.

a. The Doctrine of Compulsory Counterclaims Requires That All Causes Of Action Arising From The Same Transaction Or Occurrence Be Brought In The Same Action Before The Same Bench.

The policy underlying the compulsory counterclaim rule is judicial economy. *Transamerica Occidental Life Ins. Co. v. Aviation Office of America, Inc.*, 292 F.3d 384 (3rd Cir. 2002) *citing* Fed. R. Civ. P. 1 ("[The Federal Rules of Civil Procedure] shall be construed and administered to secure the just, speedy, and inexpensive determination of every action"). At the very least, determining whether infringement is occurring is a necessary step in resolving the claims ViaCell has presented in its amended complaint in this case. As a result, all of ViaCell's allegations supporting this motion for a preliminary injunction are actually "compulsory counterclaims" which must be raised in ViaCell's Answer to PharmaStem's Massachusetts Complaint. ViaCell's motion for a preliminary injunction arises from an action which could have and should have been brought in Massachusetts, as part of that action, given the relationship between PharmaStem's patent infringement claims and ViaCell's antitrust and unfair competition claims based on PharmaStem's patent enforcement activities.

There is no question that both PharmaStem's earlier-filed Massachusetts Complaint for patent infringement and ViaCell's later-filed action for antitrust and unfair competition arise from the same "transaction or occurrence."⁷ Both of these claims hinge largely, if not entirely, on a single determination: whether medical providers infringe PharmaStem's asserted patents by

⁷ Rather than file a response to PharmaStem's Complaint in the 2004 Massachusetts action, ViaCell sought and was granted a sixty day extension, only to bring this action, rather than bring these claims in the earlier filed Massachusetts case.

promoting the service of or collecting cord blood for storage at unlicensed banks. For Plaintiffs' claims here to qualify as compulsory counterclaims in the 2004 Massachusetts action, "there need not be a precise identity of facts between the claim and the counterclaim; rather the relevant inquiry is whether the counterclaim bears a logical relationship to an opposing party's claim." *Transamerica Occidental Life Ins. Co.*, 292 F.3d at 389 (3rd Cir. 2002) *quoting Xerox Corp. v. SCM Corp.*, 576 F.2d 1057, 1059 (3rd Cir. 1978) (internal punctuation omitted). There is more than a "logical relationship" between the claims here; PharmaStem's claims in Massachusetts and ViaCell's claims here involve an *identical* inquiry. If providers *do* infringe (as PharmaStem asserts in the 2004 Massachusetts action), PharmaStem has every right to sign settlement agreements where providers agree not to knowingly promote or collect blood for storage at the four blood banks which have refused to enter into licensing agreements with PharmaStem (precisely contrary to ViaCell's assertions here).⁸ That is, if infringement is occurring, it is not only PharmaStem's *right*, but its *duty* under its licensing agreements to enforce its patents against unlicensed infringers. On the other hand, Plaintiffs can only prevail in this action on their antitrust and unfair competition claims if *no* infringement is occurring and, *inter alia*, there was some form of bad faith on the part of PharmaStem (otherwise, obviously, PharmaStem is within its rights settling actual and potential litigation with potential infringers). Thus, final determination of *either* of these cases will necessarily involve determination of the other. Ultimately, having ViaCell's claims go forward in Massachusetts where they should have been brought initially would result in judicial economy.

b. The "First Filed" Rule Requires That The District Court In Which The First Action Is Filed Have Jurisdiction Over The Action And All Compulsory Counterclaims.

The Third Circuit has adopted the "first filed" rule, which provides that "[i]n all cases of federal concurrent jurisdiction the court which first has possession of the subject must decide it."

⁸ PharmaStem both hopes and expects that providers who sign these agreements will collect blood for storage at one of the *sixteen banks* which *have* signed license agreements.

Crosley Corp. v. Hazeltine Corp., 122 F.2d 925, 929 (3d Cir. 1941), *quoting Smith v. McIver*, 22 U.S. (9 Wheat) 532, 6 L.Ed. 152 (1824)). The policy embodied by the first filed rule is designed to ensure that a single determination is made with regard to a controversy rather than multiple determinations by different courts, which may conflict, require duplicative litigation and delay the ultimate resolution of the case. *Id.* at 929.

The potential for conflicting, duplicative litigation and delay is precisely the problem, and apparently what Plaintiffs are banking on here. Potential patent infringement is at the very heart of ViaCell's motion, and its underlying complaint. Similarly, potential patent infringement is the explicit subject matter of PharmaStem's action in Massachusetts. In deference to the District Court for the District of Massachusetts, this Court should dismiss the underlying case, and as a result, should deny this Motion for a Preliminary Injunction. If ViaCell or any other plaintiff wishes to seek a preliminary injunction, it should do so in the District of Massachusetts (or Florida or Pennsylvania, depending upon the party), the District in which its claims would have appropriately been brought. *See Crosley Corp. v. Hazeltine Corp.*, 122 F.2d 925, 929 (3d Cir.1941).

At the very core of ViaCell's motion is ViaCell's claim that "there is no basis in any of the PharmaStem patents for the assertion that healthcare providers could be liable simply for collecting cord blood and providing it to ViaCell or the other [unlicensed] blood banks." ViaCell's motion at 14. That, however, is the precise question to be decided in the suits that PharmaStem has filed in Pennsylvania, Florida, and Massachusetts. It is important to note that PharmaStem has *not* asserted the '681 and '553 Patents against providers, which were previously at issue before this Court in the 2002 Delaware action. Indeed, ViaCell, in fact, admits as much. *See* ViaCell's motion at 14.

As a result, ViaCell and the other plaintiffs in the underlying suit are essentially seeking an advisory opinion as to whether obstetricians can be liable for patent infringement in three actions pending in other jurisdictions, which is impermissible. *Presbytery of New Jersey v. Florio*, 40 F.3d 1454, 1463 (3d. Cir. 1994)("the case must involve a real and substantial

controversy admitting of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts."). Permitting ViaCell and its fellow plaintiffs to go forward with their claims in this action (and, by extension, permitting the instant motion for a preliminary injunction) serves no legitimate purpose and can only create the possibility for conflicting holdings. If ViaCell desires preliminary injunctive relief, it should seek it, if at all, in the District of Massachusetts where PharmaStem has asserted the patent rights that Plaintiffs have tried to make an issue here.

3. ViaCell Is Guilty Of Unclean Hands And In Engaging The Same Type Of Conduct That It Claims Constitutes An Antitrust Violation And Unfair Competition.

a. ViaCell Is Offering Awards To Those Who Challenge PharmaStem's Claims Of Patent Infringement And Lose.

ViaCell cannot seek the equitable remedy of a preliminary injunction in this Court because ViaCell is approaching this Court with unclean hands. *Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.*, 65 S.Ct. 993, 998 (1945) ("he who comes into equity must come with clean hands.") ViaCell's claim that PharmaStem's activities in creating, publicizing, and enforcing "Amnesty Agreements," and setting forth press releases which provide facts regarding this action which are beneficial to PharmaStem ring hollow because ViaCell has been doing exactly the same thing, although in a far more destructive and *prima facie* illegal manner. *See* Rovner Decl., Exhs. E-H.

As of at least October 25, 2004, ViaCell (on its ViaCord website) has posted information and forms regarding a legal-indemnification program that it disingenuously refers to as "The Patient Comes First" program which offers a \$100,000 prize to those who lose their claim of non-infringement of PharmaStem's Patents. In addition to "full indemnification" for liability and absolving providers of "financial risk from PharmaStem litigation," ViaCell is, shockingly, offering a prize of \$100,000 in "remuneration." This prize will be paid *in addition* to ViaCell's full indemnification and is to be "awarded to [the provider] in the unlikely event that PharmaStem prevails in a legal action against [the provider]." Thus, ViaCell is handing out an

award to infringers of PharmaStem's patents who lose suits brought by PharmaStem. *See* Rovner Decl., Exh. E. ViaCell's program is nothing more than a mechanism for doctors or providers to contract with ViaCell for indemnification in patent infringement lawsuits brought by PharmaStem (and a chance at a \$100,000 prize) in exchange for the doctor's or provider's agreement not to consider a cord blood bank's "PharmaStem licensure status" when evaluating it. Rover Decl., Exh. F.

While PharmaStem only learned of this program while briefing this Opposition, and thus has not fully evaluated the likely illegality of this offer in light of relevant antitrust and unfair competition laws, among other laws, it seems clear that awarding a party a \$100,000 prize *specifically* for infringing a PharmaStem patent and losing a lawsuit on infringement of that patent is, at minimum, both *prima facie* evidence of inducement to infringe and a bad act of such a nature as to render ViaCell's hands "unclean" and cause this Court to deny ViaCell's request for injunctive relief. *See Precision Instrument*, 65 S.Ct. at 998. Giving a substantial cash prize to a participant in a pending or yet-to-be-filed federal lawsuit based on the *outcome* of that lawsuit in exchange for that provider's agreement to totally disregard the intellectual property rights of PharmaStem and its licensees exhibits such a wholesale disregard for traditional notions of professionalism and business ethics. It is particularly troubling that ViaCell would pay a prize fee to those providers who are willing to infringe PharmaStem's Patents, rendering ViaCell's request for "equitable relief" a sham and barred by the doctrine of unclean hands.

b. ViaCell Has Published Untrue Statements Regarding The Patent Disputes With PharmaStem.

Additionally, the letter which purportedly introduces "The Patient Comes First" program (which is dated "September, 2004" and addressed "Dear Medical Professional," leaving open the question of just how far and wide it was distributed before being placed on the web) begins by stating that ViaCell "has won" the "PharmaStem patent litigation." *Id.* This is, at the very least, a *misleading* statement, as PharmaStem has a current patent infringement suit pending against ViaCell and various providers in Massachusetts. *See* Rovner Decl., Exh. A. Worse, the letter is

unambiguously false regarding this Court's recent ruling when it states that "[t]he Federal Court overturned in its entirety the 2003 judgment against ViaCell/Viacord[.]" Rovner Decl., Exh. E (emphasis in original).⁹ As this Court is well aware, this is misleading. While the judgment of infringement was overturned, the Court did not overturn the jury's verdict regarding the *validity* and *enforceability* of the '681 and '553 Patents. Those were left wholly untouched by this Court and stand as part of the judgment of this Court. In addition, this Court did not overturn, but ordered retrial, regarding infringement on one of the two patents in question.

In addition, ViaCell has set forth a "chronology of the PharmaStem Patent Litigation" which falsely claims that a Federal Court Order overturned "the judgment" against ViaCell because "PharmaStem had failed to prove infringement of its two patents." Rovner Decl., Exh. H. In fact, the Court held that "the record suggests that at least some of the defendants' cord blood units infringe" the '681 Patent. D.I. 545 of 2002 Delaware action. ViaCell's claim that PharmaStem is somehow acting in a way that necessitates a preliminary injunction for PharmaStem's press releases rings hollow, given that ViaCell itself consistently plays far faster and looser with the facts.

Although PharmaStem has not yet brought an action against ViaCell for these false statements, and explicitly reserves the right to so do, it is worth observing at this juncture that ViaCell's claims of injury from PharmaStem's press releases and communications with providers are significantly undermined as ViaCell has engaged in exactly the same type of actions, only more egregiously.

⁹ Similar statements are made in other public documents disseminated to the public. *See* Rovner Decl., Exhs. C, F, G, I.

B. VIACELL'S MOTION FOR PRELIMINARY INJUNCTION SHOULD BE DENIED BECAUSE VIACELL CANNOT ESTABLISH (1) A LIKELIHOOD OF SUCCESS, (2) IRREPARABLE HARM, (3) GREATER HARM THAN THAT TO PHARMASTEM IF THE MOTION IS GRANTED, AND (4) THAT THE PUBLIC INTEREST IS SERVED BY THE GRANTING OF THE INJUNCTION.

Whether a preliminary injunction should issue turns upon four factors: (1) the movant's reasonable likelihood of success on the merits; (2) the irreparable harm the movant will suffer if preliminary relief is not granted; (3) the balance of hardships tipping in its favor; and (4) the adverse impact on the public interest. *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1451, n. 12 (Fed. Cir. 1988); *New England Braiding Co., Inc. v. A. W. Chesterton Co.*, 970 F.2d 878, 882 (Fed. Cir. 1992). The burden is always on the movant to show that it is entitled to a preliminary injunction. *H. H. Robertson Co. v. United Steel Deck, Inc.*, 820 F.2d 384, 388 (Fed. Cir. 1987).

1. ViaCell Cannot Establish A Likelihood Of Success On The Merits On Its Sherman Act Claim Because PharmaStem's Conduct Does Not Invoke Antitrust Liability When It Enforces Its Presumably Valid, Enforceable Patents And Cannot Establish Likelihood Of Success On Its State Law Claim Because The Alleged Activity Took Place Outside Of Massachusetts.

a. PharmaStem Has A Statutory Right To Exclude Others From Practicing Its Invention Claimed In Its Valid And Enforceable Patents.

By statute, PharmaStem's patents at issue are presumably valid because PharmaStem properly, and not fraudulently, received its patents from the Patent Office, and thus enjoys a presumption of validity that attaches to an issued patent. 35 U.S.C. §282. As such, PharmaStem's Patents that have been asserted against hospitals and doctors are accorded such a presumption. Indeed, in the 2002 Delaware Action, ViaCell, Cryo-Cell and CorCell, as infringement defendants, failed to overcome the '681 and '553 Patents' presumption of validity and these patents have been deemed valid and enforceable by this Court. *See* D.I. 545 in 2002 Delaware action.

b. PharmaStem's Rightful Patent Enforcement Does Not Invoke Any Antitrust Liability

PharmaStem's conduct in connection with enforcement of its patent portfolio is immune from antitrust liability and is permitted under patent and antitrust laws.¹⁰ The patent grant "is an exception to the general rule against monopolies" and a restraint that results from a patent is normally not an antitrust violation. *Walker Process Equip., Inc. v. Food Machinery and Chem. Corp.*, 382 U.S. 172, 177 (1965). The "antitrust laws do not negate the patentee's right to exclude others from patent property." *In re Independent Service Organizations Antitrust Litigation CSU, LLC* ("ISO"), 203 F.3d 1322, 1325 (Fed. Cir. 2000). In fact, "the aims and objectives of patent and antitrust laws may seem, at first glance, wholly at odds. However, the two bodies of law are actually complimentary, as both are aimed at encouraging innovation, industry and competition." *Atari Games Corp. v. Nintendo of America, Inc.*, 897 F.2d 1572, 1572 (Fed. Cir. 1990).

The antitrust laws respect the long-standing protections afforded to intellectual property by Article I, §8 of the United States Constitution and the patent laws. A patentee is immune from antitrust liability unless it can be shown that (1) the patent was obtained by knowing and willful fraud on the Patent Office; (2) the infringement suit was a mere "sham" or (3) illegal tying. *ISO*, 203 F.3d at 1326-27. It is the antitrust plaintiff's burden to show that "one of these exceptional situations exists and, in the absence of such proof, [the court] will not inquire into the patentee's motivations for asserting his statutory right to exclude." *ISO*, 203 F.3d at 1327-28. ViaCell has failed to provide such proof to support its motion and the requisite elements of a Sherman Act violation. *Id.*

¹⁰ Federal Circuit law applies to the question of whether a patentee's conduct has antitrust implications. *In re Independent Service Organizations Antitrust Litigation*, 203 F.3d 1322, 1352 (Fed. Cir. 2000); *Nobelpharma AB v. Implant Innovations*, 141 F.3d 1059, 1068-69 (Fed. Cir. 1998)(en banc)("Whether conduct in procuring or enforcing a patent is sufficient to strip a patentee of its immunity from the antitrust laws is to be decided as a question of Federal Circuit law."). However, law of the appropriate regional circuit is applied to "issues involving other elements of antitrust law such as relevant market, market power, damages, etc., as those issues are not unique to patent law." *Nobelpharma*, 141 F.3d at 1068.

ViaCell claims in its motion that PharmaStem's enforcements of its patents constitute unreasonable restraints of trade in violation of the antitrust laws. All of PharmaStem's actions identified by them as "anticompetitive" are not, as a matter of law, antitrust violations and do not support any antitrust or unfair competition claim.

(1) PharmaStem's Patent Infringement Suits Against Private Cord Blood Banks, Hospitals And Doctors Are Not Unlawfully Anticompetitive.

PharmaStem has the right to file lawsuits in good faith against those it believes is infringing its patents. "The law recognizes a presumption that the assertion of a duly granted patent is made in good faith...this presumption is overcome only by affirmative evidence of bad faith. *C.R. Bard*, 157 F.3d at 1369; see *Atari Games Corp. v. Nintendo of America, Inc.*, 897 F.2d 1572, 1577 (Fed. Cir. 1990)(As "patents are cloaked in a presumption of validity, a patent infringement suit is presumed to be brought in good faith."). In fact, a "patent owner who brings suit to enforce the statutory right to exclude others from making, using, or selling the claimed invention is exempt from the antitrust laws, even though such suit may have an anticompetitive effect, unless the infringement defendant proves one of two conditions: (1) patent was obtained through knowing and willful fraud on the PTO or (2) infringement suit was a mere sham." *ISO*, 203 F.3d at 1326; *Nobelpharma*, 141 F.3d at 1068.¹¹

A sham lawsuit must be both subjectively brought in bad faith and based on a theory of either infringement or validity that is objectively baseless. *ISO*, 203 F.3d at 1326; *Nobelpharma*, 141 F.3d at 1072. A lawsuit is objectively baseless or meritless if "no reasonable litigant could expect success on the merits." *C.R. Bard*, 157 F.3d at 1368. "[I]f a suit is not objectively

¹¹ Indeed, "[p]atentees must be permitted to test the validity of their patents in court through actions against alleged infringers. Their status as alleged possessors of a legal monopoly does not cause them to be pariahs before the law." *Handguards, Inc. v. Ethicon, Inc.*, 601 F.2d 986, 993 (9th Cir. 1979). "It is within the rights of a patent holder to sue alleged infringers of valid patents; it is within the power of the various courts to sanction the patent holder if its allegations of infringement are baseless or if its patents are found to be unenforceable." *Augustine Medical, inc. v. Mallinckrodt, Inc.*, 2003 WL 1873836 *1, *8 (D.Del. 2003).

baseless, an antitrust defendant's subjective motivation is immaterial." *ISO*, 203 F.3d at 1326; *Nobelpharma*, 141 F.3d at 1072.

ViaCell has not asserted that patents in PharmaStem's portfolio had been obtained through knowing and willful fraud. Notably, in the 2002 Delaware Action, the '681 and '553 Patents were found not to have been acquired by knowing and willful fraud on the Patent Office. D.I. 545 in 2002 Delaware action. Furthermore, ViaCell has not brought a formal sham litigation claim against PharmaStem in this case for any objectively baseless and subjectively bad faith lawsuits, only alluding to the alleged inappropriateness of PharmaStem's infringement suits against the cord blood banks, hospitals and doctors. Thus, ViaCell has failed to provide any evidence to substantiate the "anticompetitive effect" needed to support its claims and cannot point to the requisite clear and convincing evidence of bad faith.

There is abundant evidence that PharmaStem has a good faith belief in its claims, and that good-faith belief is well founded. For example, in the 2002 Delaware action, the jury's verdict regarding the validity and enforceability of the '681 and '553 Patents remained undisturbed. Even before any appeal is filed, the net result of the 2002 Delaware action, even *with* this Court's partial reversal of the jury's verdict, is that it provides PharmaStem with significantly *more* confidence in the validity and enforceability of this family of patents. While reasonable minds could differ regarding the possibility of infringement of the asserted patents by providers and physicians, there is no clear and convincing evidence to establish that PharmaStem brought its cases against providers in "bad faith." To the contrary, the history of this case before this very Court establishes, at *minimum*, PharmaStem's good faith in enforcing its patents.

With respect to the patents that were not litigated in the 2002 Delaware action, PharmaStem does have a good faith belief in the validity of the claims against physicians, providers, and certain cord blood banking services. This is demonstrated by its enforcement of its patents, and entering into license agreements, settlement agreements with providers and Amnesty Agreements. The Federal Circuit has said that for a party to be said to have possessed "bad faith" regarding its litigation, the party asserting bad faith "must offer clear and convincing

evidence" that plaintiff "had *no reasonable basis* to believe" that plaintiffs' patents were infringed. *Golan v. Pingel Enterprise, Inc.*, 310 F.3d 1360, 1371 (Fed. Cir. 2002)(emphasis added). That is a very high bar, and one which ViaCell and its fellow plaintiffs in the underlying action simply cannot meet.

Where, as here, "[t]here is no direct evidence of bad faith or an intent to restrain or monopolize trade," the Court cannot find liability. *Procter & Gamble Co. v. Paragon Trade Brands, Inc.*, 61 F.Supp.2d 102, 108 (D. Del. 1996). Considering that ViaCell is seeking a preliminary injunction and thus bears the burden of demonstrating a likelihood of success on the merits, it must thus demonstrate "direct evidence of bad faith or an intent to restrain or monopolize trade." *Id.* ViaCell cannot come close to clearing this high bar, as there is no clear and convincing evidence of "bad faith" on the part of PharmaStem, and certainly no evidence of an "intent to restrain or monopolize trade" beyond that to which PharmaStem is explicitly allowed by the grant of its Patents.

(2) Entering Into Settlement Agreements With Private Cord Blood Banks, Hospitals And Doctors Is Not Unlawfully Anticompetitive.

PharmaStem's "Amnesty Agreements" with physicians and other health care providers are simply good-faith attempts to settle pending and potential litigation.¹² Because PharmaStem has pursued the enforcement of its intellectual property rights in demonstrable good faith, its settlement agreements do not violate Section 1 of the Sherman Act, 15 U.S.C. § 1 or the Massachusetts Unfair and Deceptive Trade Acts and Practices statute, Mass. Gen. Laws Chapter 93A ("Chapter 93A"), §§ 2 and 11. ViaCell cannot, as described herein, meet the high bar set by the Federal Circuit to prove "bad faith" on the part of a patentee, and therefore cannot

¹² Not unlike PharmaStem, ViaCell itself has "exclusive agreements" where certain providers only use ViaCell's services, such as the exclusive agreement with FemPartners. *See* Rovner Decl., Exh. E. Thus, ViaCell cannot possibly take the position that PharmaStem's encouragement to providers to work exclusively with licensed banks (of which, notably, there are sixteen) comprises some unfair use of its market power, where it is enforcing legitimate patent rights. To the extent the contrary is true, then ViaCell is also guilty of anticompetitive conduct.

demonstrate a "likelihood of success."

As a matter of sound public policy "[t]he settlement of disputes is legitimate conduct. Indeed, the law encourages the settlement of disputes." *Proctor & Gamble*, 61 F.Supp.2d at 108 (no Sherman Act § 1 claim involving settlement agreement of patent dispute), *quoting Hemstreet v. Spiegel, Inc.*, 851 F.2d 348, 350 (Fed.Cir. 1988) (internal punctuation omitted). PharmaStem in good faith has entered into agreements with parties with whom it has actual and potential disputes. The law encourages precisely this behavior. *See Proctor & Gamble Co.*, 61 F.Supp.2d at 108. Where, as here, the agreements are, on their face, settlement agreements, "the Supreme Court has admonished courts not to infer illegality from actions that, on their face, are not indicative of monopolization [...] Allowing inferences of illegality to be drawn from ambiguous evidence could deter or penalize perfectly legitimate conduct." *Id.* (internal punctuation omitted). Thus, entering into these license agreement does not support any claim involving unlawful anticompetitive conduct.

In fact, PharmaStem has been operating in demonstrable *good faith* throughout these proceedings. PharmaStem *does* have the right to communicate with potential infringers regarding its patents, the right to enforce its patents against infringers, and the right to reach settlement agreements as an alternative to litigation. *See Proctor & Gamble Co.*, 61 F.Supp.2d at 108. As such, the various settlements and offers to settle PharmaStem's good-faith patent disputes "should not be used to infer an agreement to fix royalty rates or to discriminatorily enforce patents to restrain competition." *See id.* at 109. Because PharmaStem's "Amnesty Agreements" with potential litigants "resolv[e] actual or reasonably foreseeable intellectual property disputes," these agreements cannot, as a matter of law, serve as a basis for ViaCell's (and the other plaintiffs') claims in this case. *Id.*

(3) The Terms of The Settlement Agreements Are Not Unlawfully Anticompetitive To Support An Antitrust Violation And Do Not Create An Illegal Boycott.

ViaCell loosely refers to "coerced boycott" and "illegal boycott" throughout its motion when discussing PharmaStem's Amnesty Agreements as unreasonable restraints in trade and constituting "prototypical antitrust violations." *See e.g.*, ViaCell's motion at 19. A simple review of antitrust law on illegal boycotts reveals that such allegations have no place in this case as they do not apply to the facts here and the terms of the settlement agreements fall within PharmaStem's legal right to enforce and protect its patents.

"Virtually all business agreements restrain trade to some extent; Section 1, therefore, has been construed to make illegal only those contracts that constitute unreasonable restraints of trade." *Orson, Inc. v. Miramax Film Corp.*, 79 F.3d 1358, 1366 (3d Cir. 1996). Horizontal group boycotts receive illegal *per se* treatment. *Orson*, 79 F.3d at 1367, n.9. A horizontal boycott "is when independent businesses at the same market level agree to boycott another business, also at the same level of distribution. *CCPI Inc. v. American Premier, Inc.*, 967 F. Supp. 813 (D. Del. 1997). The providers are not at the same market level as ViaCell, a private cord blood bank, and therefore there is no horizontal boycott to speak of. Moreover, when a patent is involved, the area of *per se* antitrust illegality is limited to instances where enforcement involves a fraudulently obtained patent or sham litigation. *See Walker Process*, 382 U.S. at 178. As discussed above, there is not fraud or sham litigation involved in this case.

Agreements between entities at different market levels are termed "vertical restraints" which are evaluated under the rule of reason. *Orson*, 79 F.3d at 1368. "In rule of reason cases, the plaintiff bears the initial burden of showing that the alleged combination or agreement produced adverse, anticompetitive effects within the relevant product and geographic markets." *Id.* at 1367. Antitrust plaintiffs may satisfy this burden by "proving the existence of actual anticompetitive effects" or "proof of the defendant's 'market power.'" *Id.* at 1367.

As described above, PharmaStem's enforcement actions cannot be considered unlawfully anticompetitive. Furthermore, PharmaStem does not have monopoly power in the relevant

market, which ViaCell has identified in this case as the provision of private cord blood banking services. The relevant market is the set of products consumers see as interchangeable with the putative monopolist's product in the geographic area in which consumers will buy those products. *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 394-95 (1956)), *cert. denied*, 479 U.S. 1031, 1034 (1987). Most significant in the determination of the existence of monopoly power is PharmaStem's share of the relevant market. *Pastore v. Bell Telephone Co. of Pennsylvania*, 24 F.3d 508, 513 (3d Cir. 1994). PharmaStem does not have a market share in the alleged relevant market for the provision of cord blood banking services, as it does not provide private cord blood banking services, it does not engage in the processing and cryopreservation of cord blood for future therapeutic uses and it does not have any plans to operate a private cord blood bank in the future.¹³

Thus, ViaCell has offered no evidence that PharmaStem has entered or potential future entry into the cord blood banking service market. As such, PharmaStem does not offer a product or service that is reasonably interchangeable with the ViaCell's private cord blood banking service. Since PharmaStem does not have a competing product, it does not have the ability to take significant business away from the ViaCell. For these reasons, ViaCell has not pled, much less established, that it even has grounds for its antitrust claims.

Furthermore, PharmaStem does not possess monopoly power in the relevant market for the provision of cord blood banking services by virtue of its valid patents. The law simply does not support such an allegation. "A patent alone does not demonstrate market power." *ISO*, 203 F.3d at 1325-26. A "patent grant is a legal right to exclude, not a commercial product in a competitive market." *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1355 (Fed. Cir. 1999). "It is not presumed that the patent-based right to exclude necessarily establishes market power in antitrust terms." *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1368 (Fed. Cir. 1998);

¹³ To the extent similar allegations of antitrust violations were rejected by the jury in the 2002 Delaware action, ViaCell is hard-pressed to demonstrate that it is likely to succeed on the merits of its most recent antitrust claims.

Abbott Labs. v. Brennan, 952 F.2d 1346, 1354 (Fed. Cir. 1991)(absent a presumption of market power, antitrust plaintiff alleged insufficient facts to satisfy the elements of an antitrust violation). "The commercial advantage gained by new technology and its statutory protection by patents do not covert the possessor thereof into a prohibited monopolist." *Abbott*, 952 F.2d at 1354. "Unless the patent had been obtained by fraud such that the market position had been gained illegally, the patent right to exclude does not constitute monopoly power prohibited by the Sherman Act." *C.R. Bard*, 157 F.3d at 1368. Because PharmaStem does not have monopoly power and is pursuing its claims in good faith, ViaCell does not have a claim for violation of the Sherman Act.

(4) PharmaStem's Statements On Enforcing Its Patents Do Not Invoke Antitrust Liability.

ViaCell's motion for a preliminary injunction depends on its allegation that PharmaStem is not entitled to make statements about the patent infringement liability that obstetricians and hospitals face when they work with and/or promote the service of unlicensed cord blood banks, and the fact that ViaCell and the other defendants in the underlying actions are unlicensed banks.

PharmaStem, however, has the legal right and obligation to contact the obstetricians and others regarding their potential infringement of PharmaStem's patents, and cannot be held liable for doing so unless ViaCell can demonstrate that PharmaStem did so in bad faith. *Golan v. Pingel Enterprise, Inc.*, 310 F.3d 1360, 1370-71 (Fed. Cir. 2002)("federal patent law bars the imposition of liability [under federal or state law] for publicizing a patent in the marketplace unless the plaintiff can show that the patent holder acted in bad faith."), *quoting Zenith Elecs. Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1353 (Fed. Cir. 1999); see also *Mikohn Gaming Corp. v. Acres Gaming, Inc.*, 165 F.3d 891, 897 (Fed. Cir. 1998); *Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318, 1336 (Fed. Cir. 1998); *Concrete Unlimited, Inc. v. Cementcraft, Inc.*, 776 F.2d 1537, 1538 (Fed. Cir. 1985)("a patent owner has the right to enforce its patent, and that includes threatening alleged infringers with suit.")

As a matter of Federal Circuit law, Viacell must establish PharmaStem's *bad faith* in order to demonstrate a likelihood of success on the merits in this action, which it has failed to do, as discussed herein. The Federal Circuit has held that "federal patent law preempts state-law tort liability for a patentholder's good faith conduct in communications asserting infringement of its patent and warning about potential litigation." *See, e.g., Zenith Elecs. Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1355 (Fed.Cir.1999). As such, state-law claims such as ViaCell's (and the other plaintiffs') in the underlying action can survive federal preemption only to the extent that those claims are based on a showing of "bad faith" action in asserting infringement. *Globetrotter Software, Inc. v. Elan Computer Group, Inc.* 362 F.3d 1367, 1374 (Fed. Cir. 2004).

ViaCell must prove bad faith, "even if bad faith is not otherwise an element of the tort claim." *Id.* It cannot do so, however, because the statements which PharmaStem has made are objectively true. The August 2, 2004 press release is simply an announcement that PharmaStem initiated new lawsuits against a number of unlicensed cord blood banks, including ViaCell and the other underlying Plaintiffs, as well as obstetricians. ViaCell's motion, Exh. 3. The various letters, such as the June 1, 2004 letter, the letters offering to settle the pending litigation, and the letter and Amnesty Agreement set forth PharmaStem's position regarding potential patent liability for obstetricians. See ViaCell's motion, Exhs. 3-6.

ViaCell's motion turns on the allegation that PharmaStem is not entitled to make statements about the patent infringement liability that obstetricians and hospitals face when they work with and/or promote the service of unlicensed cord blood banks, and the fact that ViaCell is an unlicensed cord blood bank. PharmaStem, however, has the *legal right* and *obligation* to contact providers and others regarding their potential infringement of PharmaStem's Patents, and cannot be held liable for doing so unless ViaCell can demonstrate that PharmaStem did so in bad faith. *Golan*, 310 F.3d at 1370-71 ("federal patent law bars the imposition of liability [under federal or state law] for publicizing a patent in the marketplace unless the plaintiff can show that the patent holder acted in bad faith."), *quoting Zenith Elecs. Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1353 (Fed. Cir. 1999).

Furthermore, while issuing press releases and statements regarding filing a lawsuit against ViaCell may be considered aggressive, such action is not anticompetitive. *See Augustine Medical, Inc. v. Mallinckrodt Medical, Inc.*, C.A. No. 01-387-SLR, 2003 WL 1873836 *1 (D.Del. 2003) (Ex. A hereto) (court not persuaded that antitrust defendant's conduct between 1997 and 1999 was anticompetitive in nature of effect). In *Augustine Medical*, even though the court held that there were genuine issues of material fact with respect to whether the patent-in-suit was fraudulently obtained, the court rejected the antitrust counterclaimant's allegations. These allegations in support of the failed antitrust claim were "numerous lawsuits [were] filed," the "continually issued press release after press release touting the filing of its unsupportable lawsuits, misleadingly implying to consumers that all competitors were (or soon would be) off the market, mischaracterizing interim court rulings and otherwise attempting to monopolize the market and to interfere with the businesses of all manufacturers of convective warming systems," which included letters to potential infringers and defendants to discuss the patentee's patent position, settlement of the litigation, and alleged infringer's chances of success at trial. *Augustine Medical*, *4. In spite of this, the Delaware Court found the antitrust claimant's proof under the Sherman Act to be so wanting as to justify the entry of a summary judgment in favor of the patentee/antitrust defendant. *Id.* at *9.

PharmaStem's statements are neither false nor misleading, as described herein. PharmaStem's position all along has been that obstetricians and other medical professionals face potential patent liability if they continue to work with unlicensed cord blood banks, including ViaCell. PharmaStem's letters and press releases do not go into great detail regarding PharmaStem's various potential theories of patent infringement, and indeed, it would make no sense that they would, as they set forth only a business-level analysis of the case before this Court. Thus, given the context of the press releases and letters as documents for consumption by lay and businesspersons, and medical practitioners, PharmaStem's statements were each objectively true, and in no case can evince the "bad faith" resulting in an antitrust violation necessary to support ViaCell's motion for a preliminary injunction.

c. ViaCell's Sherman Act Claim Cannot Succeed Because ViaCell Cannot Prove Remaining Section 1 Elements.

Section 1 of the Sherman Act, 15 U.S.C. §1 reaches unreasonable restraints of trade caused by a "contract, combination ... or conspiracy" and does not regulate wholly unilateral conduct. *Proctor & Gamble*, 61 F. Supp.2d at 106. Section 1 prohibits all concerted acts that unreasonably "restrain" trade. *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 226, n.59 (1940). In order to establish a Section 1 claim, plaintiffs must prove: (1) that there was concerted action involving PharmaStem; (2) that the concerted action caused anticompetitive effects within the relevant product and geographic markets; (3) that the objects of the conduct pursuant to the concerted action was illegal; and (4) that plaintiff was injured as a proximate result of the concerted action. *Petruzzi IGA Supermarkets v. Darling-Delaware Co.*, 998 F.2d 1224, 1229 (3d Cir. 1993).

ViaCell has not demonstrated a *prima facie* Section 1 violation. As discussed above, none of PharmaStem's enforcement conduct result in anticompetitive effects within the relevant market. As described herein, PharmaStem had a business justification for its conduct which was done in good faith, therefore defeating ViaCell's antitrust claim.

d. ViaCell's Massachusetts State Law Claims Cannot Succeed Because PharmaStem's Statements Are True And ViaCell Cannot Prove That PharmaStem's Alleged Conduct Took Place Primarily And Substantially Within The Commonwealth Of Massachusetts.

PharmaStem's alleged activity in the marketplace does not give rise to liability under Mass. Gen. Law Ch. 93A ("Chapter 93A") because Chapter 93A is only applicable when the "actions and transactions" complained about "constituting the alleged unfair method of competition or the unfair or deceptive act or practice occurred primarily and substantially within the commonwealth" of Massachusetts and the alleged conduct in this case simply did not. *See* Mass. Gen. Law Ch. 93A, § 11.

As a threshold matter, patent liability is an issue that is in the process of being determined, as PharmaStem has recently brought a number of different lawsuits against obstetricians and medical groups for infringement of its patents. None of these cases have been resolved in a final judgment. Consequently, PharmaStem is providing its position or opinion on the liability these individuals face. Thus, it is not a false or misleading statement of fact. To the extent ViaCell argues to the contrary, then it is a true statement regarding PharmaStem's belief regarding what infringes its patents and PharmaStem has filed lawsuits based on its good faith belief. *See IMCS v. D.P. Tech. Corp.*, 264 F.Supp.2d 193, 197 (E.D.Pa. 2003)(plaintiff's advertisement that its software was protected by the patent was true and not misleading as the patent is considered valid and enforceable). PharmaStem is merely stating its position on a possible future event. While ViaCell's opinion may differ, its speculative legal analysis does not give rise to liability as there has been no determination whatsoever regarding the liability of obstetricians and medical groups of PharmaStem's patents.

ViaCell's claim under Chapter 93A must also fail because ViaCell has very specifically *not* pled activity that occurred "primarily and substantially within" Massachusetts, but a nationwide "illegal boycott" to establish "market domination" involving "tens of thousands of doctors." ViaCell's Motion for a Preliminary Injunction at 1. Under Massachusetts law, for alleged unfair or deceptive conduct to have occurred "primarily and substantially" in Massachusetts, the court will look to three factors: "(1) where the defendant engaged in unfair or unscrupulous conduct; (2) where the plaintiff was on the receiving end of this unfair or unscrupulous conduct; and (3) situs of plaintiff's losses due to unfair and unscrupulous conduct." *KPS & Associates, Inc. v. Designs By FMC, Inc.*, 318 F.3d 1, 24 (Mass. App. Ct. 2003), citing *Roche v. Royal Bank of Can.*, 109 F.3d 820, 829 (1st Cir. 1997); *Clinton Hosp. Ass'n v. Corson Group, Inc.*, 907 F.2d 1260, 1265-66 (1st Cir. 1990). While Massachusetts is ViaCell's primary place of business, that fact is, to a degree, balanced by the fact that both it and PharmaStem are Delaware corporations and PharmaStem has its primary place of business outside of Massachusetts as well. Moreover, both the first and third factors weigh *heavily* in favor of a

finding that the alleged conduct occurred "primarily and substantially" outside of Massachusetts. See *KPS & Associates, Inc.*, 318 F.3d at 24.

As to the first factor, ViaCell alleges that PharmaStem sent a letter "to over 25,000 obstetricians" nationwide. See ViaCell's motion at 4. ViaCell also admits that PharmaStem is "a Delaware corporation with a principal place of business located in Larchmont, New York." ViaCell's Complaint at 6. In fact, ViaCell does not identify a single action that allegedly took place in Massachusetts. As such, the conduct ViaCell claims contends is covered by Chapter 93A took place primarily *outside* of Massachusetts under the first factor, and as such, Chapter 93A does not apply.

As to the third factor, most, if not all, of the impact of the alleged actions also occurred *outside* of Massachusetts. Where, as here, the allegedly deceptive statements made to a Massachusetts-based company's customers occurred "primarily and substantially" *outside* Massachusetts, there is no action under Chapter 93A even though the Massachusetts business may have felt the alleged loss within Massachusetts. *Yankee Candle Co., Inc. v. Bridgewater Candle Co., LLC*, 107 F.Supp.2d 82, 88 (D. Mass. 2000), *aff'd* 259 F.3d 25 (1st Cir. 2001).

In addition, ViaCell has not specifically identified by name or location a single provider or hospital who has informed it that the provider or hospital will no longer do business with it. It is highly unlikely that the majority of, or even a significant minority of the alleged "130" physicians" ViaCell generally refers to have ceased doing business with it did so because of PharmaStem. Furthermore, there is no evidence that these physicians are even located in Massachusetts. Consequently, the third factor weighs heavily in favor of PharmaStem as well. Where, as here, by ViaCell's own admissions all alleged statements were conceived of and delivered outside of Massachusetts, and where the majority of the recipients of the message were expressly not in the state of Massachusetts, there is no action under Chapter 93A. See *Yankee Candle*, 107 F.Supp.2d at 88.

2. ViaCell Cannot Establish "Irreparable Harm" Because All Harm ViaCell Alleges Might Result From Plaintiffs' Actions Can Be Fully Remedied At Law.

"Unless necessary to protect rights against injuries otherwise irremediable, [an] injunction *should not* be granted." *State Corp. Commission of Kansas v. Wichita Gas Co.* 54 S.Ct. 321, 324 (1934), *citing Terrace v. Thompson*, 263 U.S. 197, 214 (1923) (emphasis added) (internal punctuation omitted). In the context of a request for injunctive relief, a plaintiff is threatened with "irreparable injury" only when he or she is unlikely to be made whole by an award of monetary damages or some other legal, as opposed to equitable, remedy at the conclusion of the trial. *See e.g. Holiday Inns of America, Inc. v. B & B Corp.* 409 F.2d 614 (3rd Cir. 1969); *Application of McCullough on Behalf of McCullough*, 4 F.Supp.2d 411 (W.D. Pa. 1998). Thus, the injury ViaCell alleges it will suffer can only be deemed "irreparable" if the damages are estimable only by conjecture and not by any accurate standard. *McCullough*, 4 F.Supp.2d at 415. That is simply not the case here. ViaCell has pled that PharmaStem's specific activity in securing agreements with providers using the Amnesty Agreements is the locus of ViaCell's harm. As such, ViaCell has a ready legal remedy in the form of monetary damages if the Amnesty Agreements are eventually deemed to be in violation of some provision. Any loss of market share can, in this case (where cord blood banking transactions are one-time transactions, and each year brings a defined set of new customers to the marketplace) be compensated with money as well. As such, there is no injury to ViaCell in this case which cannot be redeemed with a legal remedy, and this factor also weighs in favor of PharmaStem.

Moreover, ViaCell has not even established that there *is* any harm to ViaCell at this point. ViaCell merely sets forth the self-serving Adams affidavit for the necessary element of its claims, that it has been harmed by PharmaStem's actions in the marketplace. The Adams affidavit, however, with what appears to be a *very* careful draftsman's pen, sets forth two distinct claims in parallel: (1) that ViaCell has been contacted by a certain number of doctors, hospitals, and other providers in the past few months to terminate business relationships, and (2) that ViaCell has been contacted by a number of doctors, hospitals, and other providers regarding

during the same span of time regarding PharmaStem's claims. However, the Adams affidavit fails to put these two sets of facts together in any way that establishes they are related in such a way as to establish harm. In any case, the ghost "doctors" and "hospitals" to which Mr. Adams refers have no legal standing before this Court, as their statements are merely unsubstantiated hearsay. As such, the Adams affidavit should, as a threshold matter, be afforded little or no evidentiary value, and certainly does not establish any alleged irreparable harm.

In substance, Paragraph 6 of the Adams affidavit is the only paragraph in which Mr. Adams even tries to draw a connection between the two disparate facts of physicians ending relationships with ViaCell and physicians inquiring about ViaCell's relationship to PharmaStem and the ongoing litigation; the other paragraphs are simply set forth in the apparent hope that this Court will draw an unwarranted and unstated conclusion. Paragraph 6, however, is so carefully phrased as to call into question its validity. In Paragraph 6, the Adams affidavit sets forth the same two separate statements that are typically separated by paragraph in the document. First, the Adams affidavit states that "130 obstetricians" have terminated relationships with ViaCell over the previous "few weeks," and in the second, separate sentence in the same paragraph, the Adams affidavit states that unnamed "[d]octors have told ViaCell they are taking that position due to concerns about the risk of litigation with PharmaStem." It is unclear who the "doctors" in the second sentence are, and what "that position" referred to in the second sentence is, thus (it appears intentionally) left unclear that any of the 130 obstetricians are actually any of the "doctors" referred to in the second sentence. Mr. Adams' other statements are set forth without even that level of attempt at connection, and in the absence of further information, seem to evince mere fluctuations in the marketplace unrelated to PharmaStem's ongoing efforts to license the PharmaStem Patents.

Most tellingly, the Adams affidavit does not ever specifically tie a single specific doctor or health care provider to (a) any statement regarding PharmaStem, and (b) any decision to cease to do business with ViaCell. It is obvious that there is an *implication* there, but there is *nothing more* than an implication. That should be especially troubling given that the Adams affidavit

does not identify a single hospital, doctor, or other provider by name, such that that doctor, hospital, or provider could be deposed regarding the evidentiary black-hole left by a page and a half of hearsay. All of this, of course, leaves entirely open the question as to whether ViaCell has suffered, or can prove that it *will suffer* any harm at all, let alone irreparable harm.

3. ViaCell Cannot Establish That A "Balancing Of The Harms" Weighs In Its Favor Because PharmaStem Would Be Harmed To A Greater Extent By An Injunction Than ViaCell Would Be By The Lack Of An Injunction.

Where, as here, there is significant doubt regarding both fact and law which must be resolved before ViaCell's claims can appropriately be decided, the "balancing of the harms" carries greater significance than it otherwise would. *See Wilmington City Ry. Co. v. Taylor*, 198 F. 159 (D. Del. 1912) ("the balance of convenience or hardship is ordinarily a factor of controlling importance in cases of substantial doubt as to the laws or facts existing at the time of the application). Here, there is grave doubt regarding both facts (e.g. ViaCell's failure to identify a single party by name with whom it has lost business; whether doctors and providers infringe the newly asserted patents, etc.) and law (the Massachusetts', Pennsylvania, and Florida District Courts' construction of the claims of the newly asserted patents) which must be resolved before ViaCell's claims can be adjudicated. As such, the "balancing of the harms" is of greater importance.

ViaCell identifies the *potential* for lost business and market share as its harm. PharmaStem, on the other hand, will have been stripped of it the *entirety* of its enforceable intellectual property rights if the injunction ViaCell seeks is issued. PharmaStem licenses its technology. If PharmaStem is prevented from making and enforcing license agreements, it will cease its business operations. What ViaCell seeks amounts to a corporate death sentence for PharmaStem, at least as to a large portion of its intellectual property. ViaCell, as well as Cryo-Cell and CorCell, would like nothing more than to prevent PharmaStem from enforcing its *valid, enforceable* intellectual property rights while this action is pending because PharmaStem's patent rights are, by their nature, of a limited duration. Each minute that goes by during which PharmaStem is prevented from enforcing its patent rights equals the loss of *some amount* of

money which is discernable only by conjecture and for that reason, the true "irreparable" injury in this request for an injunction is PharmaStem's, as its licensees lost market share they are legally entitled to. *McCullough*, 4 F.Supp.2d at 415. ViaCell, on the other hand, can recover whatever business it identifies as lost via PharmaStem's Amnesty Agreements in the form of a legal remedy. As such, the balancing of the harms weighs heavily in favor of PharmaStem.

4. ViaCell Cannot Establish That The "Public Interest" Is Served By The Granting Of An Injunction Because PharmaStem Is Asserting Its Rights In A Fair And Balanced Manner Calculated To License As Many Banks As Possible.

Contrary to Plaintiffs' assertions that PharmaStem has somehow attempted to restrict the marketplace beyond what PharmaStem's patents grant, PharmaStem has actually attempted to license as many banks as possible so that its valuable, potentially life-saving technology can be used by as many people as possible. To that end, PharmaStem has successfully licensed sixteen of the twenty private cord blood banks in the country, and has made multiple overtures to ViaCell and the other plaintiffs in the underlying action attempting to license them as well.¹⁴ It is true that PharmaStem *is* enforcing its intellectual property rights by bringing suits against the *four* remaining unlicensed private cord blood banks (though obviously not the *sixteen* which are licensees), and providers who have explicitly agreed to promote and collect blood for unlicensed banks, *but that is PharmaStem's right*. PharmaStem has made a genuine effort, both for its own interests and for the public interest, to license these patents as widely as possible to as many cord blood storage banks as are willing to sit down at the negotiating table with PharmaStem. The fact that ViaCell, Cryo-Cell and CorCell, who have not licensed PharmaStem's Patents, have raised their prices for their service over the past few years undermines any claim that higher

¹⁴ Ironically, PharmaStem's communications attempting to establish a business relationship with ViaCell, the other Plaintiffs in the underlying action, and providers (through which PharmaStem would provide licenses to the plaintiffs and providers) have been met only with requests to *cease* communication by Plaintiffs. It is curious that Plaintiffs now claim that PharmaStem is unreasonably trying to restrict trade against the public interest, when these same Plaintiffs very explicitly rejected PharmaStem's overtures without any apparent significant consideration just months ago, and have now sued PharmaStem for PharmaStem's very attempts to license its patents.

prices result from entering into a PharmaStem license agreement. Thus, there is no harm to the public interest, as there are many alternatives in the marketplace. That ViaCell and the other plaintiffs in the underlying action have banded together to fight PharmaStem's patent rights to the bitter end is not PharmaStem's fault, and does not render PharmaStem's actions against them "against the public interest."

ViaCell confuses its desired outcome (a large market share of the extant and vibrant cord blood banking market) with an end that is in the public interest. While there is a public interest in widely available cord blood banking services (a fact which is at the very heart of PharmaStem's desire to widely license PharmaStem's patents), it is also very much true that constant innovation by companies like PharmaStem is in the public interest as well, and that constant innovation depends, largely, on the existence of the ability of owners of private intellectual property rights to enforce those private intellectual property rights.

The "public interest" would be no more well served by granting the injunction ViaCell seeks (stripping PharmaStem of its ability to enforce its valid, enforceable patents against those it believes, in good faith, infringe them) than would an injunction from a Federal Court taking possession of all McDonald's restaurants and turning them into public gymnasiums. While public gymnasiums *are* arguably good, the public's interest in encouraging ownership of private property far outweighs any benefit of the injunction. Similarly, while wide-spread cord blood banking is in the public interest (and again, is an explicit and obvious goal of PharmaStem) granting an injunction stripping PharmaStem of all meaningful rights in its presumptively valid and enforceable intellectual property, at the bequest of four entrenched cord blood banks (which, as a purely business decision, have decided to refuse to take licenses in the technology they are using in their business), is most certainly *not* in the public interest because doing so takes away the very incentive to innovate that help drive PharmaStem, and other similar companies, to create inventions "in the public interest" in the first place.

C. VIACELL'S MOTION FOR PRELIMINARY INJUNCTION SHOULD BE DENIED BECAUSE VIACELL'S REQUESTED INJUNCTION IS OVERBROAD AND VIOLATES FED. R. CIV. P. RULE 65.

ViaCell's requested injunction must be denied because the injunction ViaCell sets forth it is in direct contravention of Fed. R. Civ. P. 65, which requires that "[e]very order granting an injunction [...] shall set forth the reasons for its issuance; shall be specific in terms; shall describe in reasonable detail, and not by reference to the complaint or other document, the act or acts sought to be restrained." Fed. R. Civ. P. 65. Under Rule 65(d), "those against whom an injunction is issued should receive fair and precisely drawn notice of what the injunction actually prohibits" *KSM Fastening Sys., Inc. v. H.A. Jones Co., Inc.*, 776 F.2d 1522, 1526 (Fed. Cir. 1985) (quoting *Granny Goose Foods, Inc. v. Brotherhood of Teamsters*, 415 U.S. 423, 444 (1974)). This is to "minimize confusion as to how the enjoined party can conform its conduct with the order...and to minimize needless contempt proceedings." *Oakley, Inc. v. Sunglass Hut Int'l*, 316 F.3d 1331, 1346 (Fed. Cir. 2003). The Federal Circuit has held that an injunction does not comply with Rule 65(d) when it "does not use specific terms or describe in reasonable detail the acts sought to be restrained." *Additive Controls & Measurement Systems, Inc. v. Flowdata, Inc.*, 986 F.2d 476, 479-80 (Fed. Cir. 1993); *KSM*, 776 F.2d at 1526.

ViaCell's proposed injunction does not meet these standards in any of the three clauses which it sets forth because all three purport to prohibit activity in which ViaCell has a Constitutionally protected interest. ViaCell's first proposed clause (section "a") suggests that PharmaStem should be enjoined from signing any "agreements that require health care providers to stop collecting cord blood to be stored at ViaCell or otherwise stop doing business with ViaCell." However, as discussed above, PharmaStem has pending numerous lawsuits pending against providers in multiple jurisdictions on the very grounds that by promoting and collecting cord blood for storage at ViaCell (and other unlicensed cord blood banks), the providers are infringing some of PharmaStem's Patents. In other words, ViaCell is asking this Court to enjoin PharmaStem from settling its pending lawsuits against providers. ViaCell is suggesting that PharmaStem be prohibited from filing suits to enforce its *presumptively valid* intellectual

property rights on two patents which this Court has already held are valid and enforceable, two patents which are not before this Court in any infringement litigation, and one patent which is not currently before *any Court at all*. Stripping PharmaStem of the entirety of its Constitutionally-guaranteed right to bring a grievance to enforce its presumptively valid intellectual property rights against all potential infringers based on a motion for preliminary injunction is the very definition over-breadth.

Similarly, ViaCell's second proposed clause (section "b") suggesting that PharmaStem be enjoined from "enforcing, attempting to enforce, or threatening to enforce any 'Amnesty Agreements' already signed" is a wholesale evisceration of both the contract rights of not only PharmaStem, but a significant number of third parties, and the Constitutionally guaranteed right of PharmaStem to avail itself of the Court to enforce valid, formal contracts.

ViaCell's third proposed clause (section "c") is simply absurd, as it would act as a carte blanche license from the Court to a group of providers to willfully infringe PharmaStem's patents in any way they want, without any repercussions. ViaCell here is specifically asking the Court to order that "Physicians and other health care providers who have already signed 'amnesty agreements' cannot incur liability for infringement of any of PharmaStem's patents based on *any conduct* occurring prior to or during the pendency of this lawsuit." ViaCell's motion at 2 (emphasis added). Even a cursory reading of the clause should give the Court great pause, as it is immediately clear that a party with whom PharmaStem has signed an 'amnesty agreement' should most clearly not be given the ability to infringe PharmaStem's patents at will for now until however long it takes to resolve ViaCell's suit. Even if re-formed to correct that rather obvious deficiency, this clause in any significantly similar form would preclude PharmaStem's recovery from an entire class of infringers even if this Court or another holds that that party does *infringe PharmaStem's patents*. In sum, as evidenced by the gross over-breadth of the provisions ViaCell has set forth in its proposed injunction, ViaCell's motion appears largely an attempt at either outright theft or wholesale evisceration of PharmaStem's intellectual property. Regardless what ViaCell may believe about PharmaStem's conduct in sending press releases and

communications within the marketplace, that conduct cannot and does not justify this absurd result.

IV. CONCLUSION


For all of the reasons set forth above, PharmaStem respectfully requests this Court deny ViaCell's motion for a preliminary injunction.

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I hereby certify that, on October 26, 2004, true and correct copies of the within document were served on the following counsel of record at the addresses and in the manner indicated:

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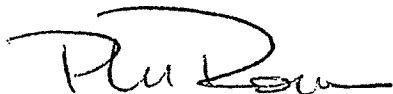
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